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[Docket No. 2OOOP-0586] (formerly Docket No. UOP-0586)

Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk

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In spite of the Federal Register title of "Proposal to Permit the Use of Ultra Filtered Milk" the docket very clearly says, "the petitioners stated that mechanical filtration has been used in cheese manufacturing in the United States for the past 20 years,". Common knowledge reveals the Food and Drug Administration (FDA) has abandoned long ago any regulatory requirement.

FDA has allowed without question the use of in-plant ultrafiltration under the ruse of "alternative make procedure", with no questions asked. FDA has also de facto allowed plant-to-plant interstate shipment and use of Ultra Filtered milk with no oversight.

FDA has ignored comments submitted as evidenced by the statement on page 11, "but none of the comments supported the NCI petition."

Then on page 28 FDA states, "In response to the petitions, FDA received some comments that opposed the use of any filtered milk, citing product safety and quality concerns, however, these comments did not provide any scientifically sound and valid data to support their objections specifically with regard to fluid UF milk. At this time, FDA does not have any information that raises food safety concerns with the use of fluid UF milk in standardized cheeses." FDA has never made any effort to require safety studies and it seems elementary that without FDA exercising their responsibility no safety study will be performed.

In an earlier Federal Register document, (Federal Register: April 17, 1997 (Volume 62, Number 74) Proposed Rules Page 18937-18964) is written "The basic thrust of the 1958 amendment was to require that, before a new additive could be used in food, its producer demonstrate the safety of the additive to FDA." The responsibility for safety oversight is FDA's and FDA cannot shift that responsibility to others.

As for quality concerns, the Federal Register states, "FDA tentatively concludes that fluid UF milk can be used in standardized cheeses while maintaining the essential characteristics of these cheeses specified in the individual standards of identity in part 133. Scientific literature suggests that fluid UF milk, especially at low concentration factors, can be used in different cheeses (including soft, semi-hard, hard, and directacidified cheeses and process cheese) without adversely affecting the physical, chemical, or organoleptic properties of the cheese (page 22).

The above follows a statement on page 20, "In addition, research suggests that milk that is concentrated to higher levels of protein is not suited for use in all types of cheeses, with adverse effects on quality being reported particularly in the case of hard and semi-hard cheeses."

Therefore, from FDA's own document, any reasonable person can conclude, quality problems are irreversibly entwined with the use of Ultra Filtered milk. It is simply a matter of degree, not of kind. At low levels the problems are there, they simply are not noticed.

The basis for this proposed rule is money. On page 35, "This increase in yield lowers costs by up to two cents per pound of cheese" which concludes with "Therefore; the yield increase due to partial replacement of milk with fluid UF milk in all U.S. cheese production could save about $172 million per year." As if to convey the idea that no stone had been left unturned "This estimate may understate the potential cost savings" is added.

If the public's interest were to be fully served, note should be taken that in the period 1998 – 2004 one petitioner, Grocery Manufacturers of America was the eighth largest spender in lobbying FDA. Add the other two and predictably, money talks, big money talks loudest.

The petitions should be withdrawn. FDA should fulfill its legal obligation as a regulator.

Sincerely,

Paul Rozwadowski

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Chair, Dairy Subcommittee